



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2014-N-0655]

Medical Devices; General and Plastic Surgery Devices; Classification of the Nonabsorbable Expandable Hemostatic Sponge for Temporary Internal Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the nonabsorbable expandable hemostatic sponge for temporary internal use into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the nonabsorbable expandable hemostatic sponge for temporary internal use classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable April 3, 2014.

FOR FURTHER INFORMATION CONTACT: Kelley Burrige, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G425, Silver Spring, MD 20993-0002, 301-796-7630.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144, July 9, 2012), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial

equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On January 30, 2013, RevMedx, Inc., submitted a request for classification of XSTAT under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 3, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 878.4452.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for a nonabsorbable expandable hemostatic sponge for temporary internal use will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name nonabsorbable expandable hemostatic sponge for temporary internal use, and it is identified as a prescription device intended to be placed temporarily into junctional, non-compressible wounds, which are not amenable to tourniquet use, to control bleeding until surgical care is acquired. The sponges expand upon contact with blood to fill the wound cavity and provide a physical barrier and pressure that facilitates formation of a clot. The device consists of sterile nonabsorbable radiopaque compressed sponges and may include an applicator to facilitate delivery into a wound.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks in table 1:

Table 1.--Nonabsorbable Expandable Hemostatic Sponge for Temporary Internal Use Risks and Mitigation Measures

Identified Risk	Mitigation Measure
Failure to Stop Bleeding or Recurrence of Bleeding	Non-Clinical Performance Data In Vivo Performance Data Stability Assessment Labeling
Obstruction of Vital Organs	Human Factors Testing Labeling
Embolization	In Vivo Performance Data
Collateral Tissue Damage (e.g., paralysis, nerve damage, tissue necrosis)	In Vivo Performance Data Labeling
Adverse Tissue and Allergic Reactions	Material Characterization Biocompatibility In Vivo Performance Data Labeling
Infection (e.g., cellulitis, Toxic Shock Syndrome, sepsis)	Sterility Testing Stability Assessment
Reoperation Due to Material Retained in Body	Non-Clinical Performance Data In Vivo Performance Data Human Factors Testing Labeling

Sponge Deployment Failure	Non-Clinical Performance Data In Vivo Performance Data Stability Assessment Human Factors Testing Labeling
Improper Application Technique or Use Error	Human Factors Testing Labeling

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

1. Performance data must demonstrate the biocompatibility of patient-contacting components.
2. Performance data must demonstrate the sterility of patient-contacting components including endotoxin and pyrogenicity assessments.
3. Performance data must support device stability by demonstrating continued sterility of the patient-contacting components of the device, package integrity, and device functionality over the requested shelf life.
4. Assessment of material characteristics must be sufficient to support safety under anticipated conditions of use. Assessments must include the following:
 - Material specifications;
 - immunogenicity; and
 - viral inactivation for animal-derived materials.
5. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - Absorption capacity;
 - extent of swelling;
 - mechanical properties;
 - expansion force/pressure;
 - radiopacity; and

- deployment/applicator functionality.
6. In vivo performance data must demonstrate safe and effective use by verifying that the device performs as intended under anticipated conditions of use. Appropriate analysis/testing must demonstrate that the product: Controls bleeding, does not promote adverse local or systemic effects, and can be completely removed from the wound. The following performance characteristics must be tested:
- Deployment;
 - control of bleeding;
 - radiopacity;
 - retrieval; and
 - assessment of local and systemic effects.
7. Human factors testing and analysis must validate that the device design and labeling are sufficient for appropriate use by emergency responders deploying the device as well as surgeons retrieving the device from wounds.
8. Labeling must include:
- Specific instructions for deployment by emergency responders and retrieval by surgeons;
 - warnings, cautions, and limitations needed for safe use of the device;
 - information on how the device operates and the typical course of treatment;
 - a detailed summary of the in vivo and human factors testing pertinent to use of the device;
 - appropriate imaging information to ensure complete retrieval of device; and
 - an expiration date/shelf life.

Nonabsorbable expandable hemostatic sponges for temporary internal use are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (§ 878.4452; see section 520(e) of the FD&C Act (21 U.S.C. 360j(e)) and 21 CFR 801.109 (Prescription devices).) Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the nonabsorbable expandable hemostatic sponge for temporary internal use they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part

807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910-0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. K130218: De novo request per 513(f)(2) of the Federal Food, Drug, and Cosmetic Act from RevMedx, Inc., dated January 28, 2013.

List of Subjects in 21 CFR Part 878

Medical devices, General and plastic surgery devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878--GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 878.4452 to subpart E to read as follows:

§ 878.4452 Nonabsorbable expandable hemostatic sponge for temporary internal use.

(a) Identification. A nonabsorbable expandable hemostatic sponge for temporary internal use is a prescription device intended to be placed temporarily into junctional, non-compressible wounds, which are not amenable to tourniquet use, to control bleeding until surgical care is acquired. The sponges expand upon contact with blood to fill the wound cavity and provide a

physical barrier and pressure that facilitates formation of a clot. The device consists of sterile, nonabsorbable radiopaque compressed sponges and may include an applicator to facilitate delivery into a wound.

(b) Classification. Class II (special controls). The special controls for this device are:

- (1) Performance data must demonstrate the biocompatibility of patient-contacting components.
- (2) Performance data must demonstrate the sterility of patient-contacting components including endotoxin and pyrogenicity assessments.
- (3) Performance data must support device stability by demonstrating continued sterility of the patient-contacting components of the device, package integrity, and device functionality over the requested shelf life.
- (4) Assessment of material characteristics must be sufficient to support safety under anticipated conditions of use. Assessments must include the following:
 - (i) Material specifications.
 - (ii) Immunogenicity.
 - (iii) Viral inactivation for animal-derived materials.
- (5) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - (i) Absorption capacity.
 - (ii) Extent of swelling.
 - (iii) Mechanical properties.
 - (iv) Expansion force/pressure.

(v) Radiopacity.

(vi) Deployment/applicator functionality.

(6) In vivo performance data must demonstrate safe and effective use by verifying that the device performs as intended under anticipated conditions of use. Appropriate analysis/testing must demonstrate that the product: Controls bleeding, does not promote adverse local or systemic effects, and can be completely removed from the wound. The following performance characteristics must be tested:

(i) Deployment.

(ii) Control of bleeding.

(iii) Radiopacity.

(iv) Retrieval.

(v) Assessment of local and systemic effects.

(7) Human factors testing and analysis must validate that the device design and labeling are sufficient for appropriate use by emergency responders deploying the device as well as surgeons retrieving the device from wounds.

(8) Labeling must include:

(i) Specific instructions for deployment by emergency responders and retrieval by surgeons.

(ii) Warnings, cautions, and limitations needed for safe use of the device.

(iii) Information on how the device operates and the typical course of treatment.

(iv) A detailed summary of the in vivo and human factors testing pertinent to use of the device.

(v) Appropriate imaging information to ensure complete retrieval of device.

(vi) An expiration date/shelf life.

Dated: June 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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